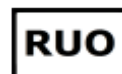


311-4 2025-05-13



For research use only

HIV REAL-TIME PCR Detection Kit

INSTRUCTION FOR USE



“DNA-Technology Research & Production”, LLC

142281, Russia,

Moscow Region, Protvino,

Zheleznodorozhnaya Street, 20

Phone/fax: +7 (495) 640-17-71

E-mail: info@dna-technology.com

<https://www.dna-technology.com>

Customer service department

E-mail: hotline@dna-technology.ru



R3-P609-23/9EU
R3-P609-S3/9EU



311-4.2025.05.13

CONTENTS

1. INTENDED USE	4
2. METHOD	4
3. CONTENT	5
4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED	6
5. WARNINGS AND PRECAUTIONS	7
6. RNA EXTRACTION PROTOCOL	9
7. REVERSE TRANSCRIPTION PROTOCOL	11
8. PCR PROTOCOL	12
9. CONTROLS	15
10. DATA ANALYSIS	12
11. TROUBLESHOOTING	16
12. STORAGE AND HANDLING REQUIREMENTS	17
13. SPECIFICATIONS	17
14. QUALITY CONTROL	18
15. KEY TO SYMBOLS	18
Annex A	20

1. INTENDED USE

HIV REAL-TIME PCR Detection Kit is an *in vitro* Nucleic Acid Test (NAT) – pathogen-detection-based product. The **HIV REAL-TIME PCR Detection Kit** is designed to detect Human Immunodeficiency Virus type 1 (HIV-1) nucleic acids in human blood plasma.

The application of the kit does not depend on population and demographic aspects. There are no contradictions for use of the **HIV REAL-TIME PCR Detection Kit**.

The **HIV REAL-TIME PCR Detection Kit** can be used in research practice.

Potential users: qualified personnel trained in molecular research methods and rules of work in the laboratory.

It is necessary to apply the kit only as directed in this instruction for use.

2. METHOD

The implemented method is based on viral RNA reverse transcription followed by PCR amplification of the obtained cDNA.

The **HIV REAL-TIME PCR Detection Kit** is based on fluorescent modification of the PCR method. The PCR-mix contains target-specific probes bearing reporter and quencher molecules. Once hybridized to a target sequence, the probes become activated. As a result of activation fluorescence increases proportionally to target sequence amplification. The intensity of fluorescence is measured at every cycle of reaction with a Real-time PCR thermal cycler data collection unit and analyzed with the software provided.

The automatic analysis for **HIV REAL-TIME PCR Detection Kit** is available on “DNA-Technology” made instruments: DTlite and DTprime Thermal Cyclers (see the catalogue at <https://www.dna-technology.com> to see available supply options). The current version of the software is available for download at <https://www.dna-technology.com/software>.

The **HIV REAL-TIME PCR Detection Kit** is also approved for use with iQ (Bio-Rad Laboratories) and Rotor-Gene Q (Qiagen) real-time thermal cyclers.

3. CONTENT

Table 1. *PREP-NA* DNA/RNA Extraction Kit¹

Reagent	Description	Total volume	Amount
Lysis buffer	Light blue slightly foaming liquid	30 mL	1 vial
Precipitation buffer	Colorless transparent liquid	40 mL	1 vial
Washout solution 1	Colorless transparent liquid	50 mL	1 vial
Washout solution 2	Colorless transparent liquid	30 mL	1 vial
Dilution buffer	Colorless transparent liquid	5 mL (1.25 mL in each tube)	4 tubes
Negative control (C-)	Colorless transparent liquid	3 mL (1.5 mL in each tube)	2 tubes
Internal control (RNA-IC)	Colorless transparent liquid	1 mL	1 tube

Table 2. Reverse Transcription Kit

Reagent	Description	Total volume	Amount
RT-buffer	Transparent colorless liquid	200 µL	1 tube
RT-HAV+HCV+HDV+HGV+HIV primers and dNTP's	Transparent colorless liquid	100 µL	1 tube
Reverse transcriptase	Transparent colorless viscous liquid	50 µL	1 tube

Table 3. HIV REAL-TIME PCR Detection Kit

Reagent	Description	Total volume	Amount
Paraffin sealed PCR-mix	Transparent colorless liquid under wax layer	1.92 mL (0.02 mL in each tube)	96 tubes or 12 8-tube strips
TECHNO Taq-polymerase	Transparent colorless viscous liquid	50 µL	1 tube
PCR-buffer	Transparent colorless liquid	1 mL (0.5 mL in each tube)	2 tubes
Positive control (C+)	Transparent colorless liquid	150 µL	1 tube
Mineral oil	Transparent colorless viscous oily liquid	2 mL (1 mL in each tube)	2 tubes
Cap strips	12 8-cap strips		

All components are ready to use and do not require additional preparation for operation.

The **HIV REAL-TIME PCR Detection Kit** designed for 96 tests, including analysis of test samples, negative controls and positive controls.

¹ - can be included into the kit if requested.

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

4.1 Specimen collection

The blood samples should be collected in 2.0 or 4.0 mL Vacuette type tubes with EDTA in 2.0 mg/mL final concentration. The sodium citrate anticoagulant is also applicable.



The use of heparin anticoagulant is not allowed.

4.2 RNA extraction and PCR

Class II biological safety cabinet;

UV PCR cabinet;

Vortex mixer;

Aspirator with trap flask to remove supernatants;

1.5 mL tubes;

Tube rack for 0.2 mL and 1.5 mL tubes;

Single channel pipettes (volume range 2-20 μ L, 20-200 μ L, 200-1000 μ L);

RNase and DNase free filtered pipette tips (volume range 20 μ L, 200 μ L, 1000 μ L);

Pipette tip without filter (for electrical laboratory aspirator);

Powder-free surgical gloves;

Disinfectant solution;

Container for used pipette tips, tubes and other consumables;

High speed centrifuge (RCF(g) 16,000);

Thermostat (temperature range from 40 °C to 95 °C);

The most recent version of the DT thermal cyclers software can be downloaded from <https://www.dna-technology.com/software>.

5. WARNINGS AND PRECAUTIONS

As part of industrial and personal hygiene and general safety practices, avoid all unnecessary exposure to the chemical components of this kit and ensure prompt removal from skin, eyes, and clothing upon contact.

Significant health effects are **NOT** anticipated from routine use of this kit when adhering to the instructions listed in the current manual.

5.1 General warnings and precautions

Handle and dispose all biological samples as if they were able to transmit infective agents. Avoid direct contact with the biological samples. Avoid producing spills or aerosol. Any material coming in contact with the biological samples must be treated for at least 30 minutes with disinfecting solution or autoclaved for 1 hour at 121°C before disposal.

Handle and dispose all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. Avoid direct contact with the reagents. Avoid producing spills or aerosol. Waste must be handled and disposed according to adequate safety measures. Disposable combustible material must be incinerated. Liquid waste containing acids or bases must be neutralized before disposal.

Wear suitable protective clothes and gloves and protect eyes and face.

Never pipette solutions by mouth.

Do not eat, drink, smoke or apply cosmetic products in the work areas.

Carefully wash hands after handling samples and reagents.

Dispose of leftover reagents and waste in compliance with the regulations in force.

Read the **Instruction for use** provided with the kit before running the assay.

While running the assay follow the instructions listed in the **Instruction for use**.

Do not use the kit after the expiry date provided.

Only use the reagents provided in the kit and those recommended by manufacturer.

Do not mix reagents from different batches.

Do not use reagents from third party manufacturers' kits.

5.2 Warnings and precautions for molecular biology

Molecular biology procedures, such as nucleic acids extraction, reverse transcription, amplification and detection require qualified staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

Equip separate areas for the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never introduce an amplification product in the area designed for extraction/preparation of amplification reactions.

Wear lab coats, gloves and tools, which are exclusively employed for the extraction/preparation of the amplification reaction and for the amplification/detection of the amplification products. Never transfer lab coats, gloves and tools from the area designed for amplification/detection of the amplification products to the area designed for extraction/preparation of amplification reactions.

The samples must be exclusively employed for certain type of analysis. Samples must be handled under a laminar flow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA.

The reagents must be handled under a laminar flow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. Pipettes used to handle reagents must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA.

Amplification products must be handled in such a way as to reduce dispersion into the environment as much as possible, in order to avoid the possibility of contamination. Pipettes used to handle amplification products must be exclusively employed for this specific purpose.

5.3 Emergency actions

Inhalation: Inhalation of the PCR-mix contained within this kit is unlikely, however care should be taken.

Eye Contact: If any component of this kit enters the eyes, wash eyes gently under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

Skin Contact: If any component of this kit contacts the skin and causes discomfort, remove any contaminated clothing. Wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

Ingestion: If any component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

6. RNA EXTRACTION PROTOCOL

The **HIV REAL-TIME PCR Detection Kit** is designed to detect cDNA extracted from blood plasma. Shake the tube containing blood sample thoroughly to mix the blood and anticoagulant.



Using of heparin as anticoagulant is not allowed.



The overall storage of the sample should not exceed 6 hours.

The transportation and storage temperature from collecting the sample till analysis should be between 2 °C and 8 °C.



Whole blood cannot be frozen.

- 6.1** To obtain the plasma spin the tubes with blood at RCF (g) 800-1600 (corresponds to 3000 rpm on Eppendorf Centrifuge 5424) for 20 min at room temperature (between 18 °C and 25 °C).



Relative centrifugal force (RCF or g) depends on rotation frequency and centrifugation radius (Annex A). To establish if your centrifuge meets the requirements apply to the exploitation manual for centrifuge.

- 6.2** Take the upper fraction (plasma) with an automatic sampler and put it into the new 1.5 mL tube. The blood plasma can be stored at minus 20 °C for 3 months.



The lysis buffer can contain the precipitate. Keep it at 65 °C until precipitate fully dissolved.



At this step of assay use only disposable pipette tips which have filter and are RNase and DNase free.



If the plasma was frozen, prior to extraction thaw it at room temperature or at temperature from 2 °C to 8 °C. Vortex the thawed plasma and centrifugate at RCF(g) 16,000 for 5 min. Take the volume needed for RNA extraction without touching the precipitate. Not more than 3 freezing/thawing cycles are allowed.



To increase the sensitivity of analysis it is necessary to carry out preliminary ultracentrifugation at 16500 rpm (24000 x g) for 1 hour at temperature between 2 °C and 8 °C.

- 6.3** Mark the required number of 1.5 mL tubes by the following scheme: for each test sample and for negative control ("C-").
For example: if you need to test 10 samples, mark 11 tubes (10 for the samples, 1 for C-).

- 6.4** Add 10 µL of the premixed internal control (RNA-IC) in each tube.
- 6.5** Add 300 µL of the lysis buffer avoiding contact of the pipette tip with an edge of the tube. Close the tubes.



Open the tube, add sample, then close the tube before proceeding to the next DNA sample to prevent contamination.

- 6.6** Add 100 µL of the premixed blood plasma sample into the marked tubes. Do not add samples to the “C-” tube.
- 6.7** Add 100 µL of the “C-” into corresponding tube.
- 6.8** Close the tubes and vortex them maximally intensively for 3–5 sec twice.
- 6.9** Incubate the tubes for 15 min at 65 °C, spin down the drops at RCF(g) 16,000 for 30 sec at room temperature.
- 6.10** Add 400 µL of the precipitation buffer into each tube. Close the tubes and vortex them maximally intensively for 3-5 sec twice.
- 6.11** Spin the tubes at RCF(g) 16,000 for 15 min at room temperature.
- 6.12** Remove the supernatant avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.
- 6.13** Add 500 µL of the washout solution №1 to the precipitate. Vortex the tubes for 3–5 sec. Invert the tube up and down washing of the cap of the tube. It is necessary to carry out this procedure with each tube individually.
- 6.14** Spin the tubes at RCF(g) 16,000 for 5 min at room temperature.
- 6.15** Remove the supernatant avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.
- 6.16** Add 300 µL of the washout solution №2 to the precipitate. Vortex the tubes for 3–5 sec. Gently invert the tube up and down washing of the walls and the cap of the tube. It is necessary to carry out this procedure with each tube individually.
- 6.17** Spin the tubes at RCF(g) 16,000 for 5 min at room temperature.
- 6.18** Remove the supernatant avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.
- 6.19** Open the tubes and dry the precipitate at 65 °C for 5 min strictly.
- 6.20** Add 16.5 µL of the dilution buffer to the precipitate. Spin down the drops for 3–5 sec.
- 6.21** Incubate the tubes for 10 min at 65 °C, vortex them maximally intensively.
- 6.22** Spin down the drops at RCF(g) 16,000 for 30 sec.



The RNA preparation is ready. RNA should be use immediately for reverse transcription reaction, RNA sample shouldn't be stored!



For several infections testing add 50 µL of the dilution buffer to the precipitate. Keep in mind that increasing of the buffer volume results in the proportional dilution of the sample and reducing analysis sensitivity. Analytical sensitivity 200 copies/mL is verified for dilution buffer volume equal 16.5 µL.

7. REVERSE TRANSCRIPTION PROTOCOL

- 7.1** Thaw content of “RT-buffer” and “RT-HAV+HCV+HDV+HGV+HIV primers and dNTP” tubes from Reverse Transcription Reagent Set at room temperature, then vortex thoroughly and spin down drops for 3-5 sec.



The RT buffer can contain the precipitate. Keep it at room temperature with intermittent vortexing until precipitate fully dissolved.

- 7.2** Prepare the mixture of “RT-Buffer”, “RT-HAV+HCV+HDV+HGV+HIV primers and dNTPs” and reverse transcriptase (RT-mix). Add into the one plastic tube:

2.0 x (N+1) µL “RT-Buffer”;

1.0 x (N+1) µL “RT-HAV+HCV+HDV+HGV+HIV primers and dNTPs”;

0.5 x (N+1) µL reverse transcriptase,

N – the number of samples being analyzed, considering “C-”.



Reverse transcriptase should be kept out of freezer chamber for as short time as possible.

- 7.3** Vortex RT-mix and spin down drops for 3-5 sec at room temperature.
- 7.4** Add 3.5 µL of the RT-mix to each tube with isolated RNA sample and to “C-” tube. Vortex the tube and spin down the drops.
- 7.5** Place tubes in thermostat and incubate at 40 °C for 30 min, then heat up to 95 °C and leave for 5 min.
- 7.6** Spin the tubes at RCF(g) 16,000 for 30 sec to collect the drops.

The cDNA preparation is ready for PCR.



The storage of the cDNA preparation is allowed at temperature from minus 18 °C to minus 22 °C for no longer than 1 month.

8. PCR PROTOCOL



1. The reagents and tubes should be kept away from direct sun light.
2. When using package S, strips, strictly observe the completeness of the strips and caps. Do not use the caps for the strips of the other kits!

8.1 Mark tubes/stripped tubes with PCR-mix for each test sample, negative control (C-) and positive control (C+).

For example if you need to test 10 samples, mark 12 tubes (10 for each sample, 1 for "C-", 1 for "C+").

8.2 Thaw PCR-buffer at the room temperature.

8.3 Mix the PCR-buffer and TECHNO Taq-polymerase thoroughly (3-5 sec), then spin briefly (1-3 sec) at room temperature.



Hold TECHNO Taq-polymerase at room temperature as short time as possible. The overheating is detrimental to its performance.

8.4 Prepare the mixture of PCR-buffer and TECHNO Taq-polymerase (Taq-polymerase solution). Add into the one tube:

- 10 x (N+1) μ L of PCR-buffer;
- 0.5 x (N+1) μ L of TECHNO Taq-polymerase,

N — number of the marked tubes including C-, C+, background tubes.

For example if you need to test 10 samples (12 marked tubes), prepare mixture of PCR-buffer and TECHNO Taq-polymerase for 13 (12+1) tubes: 130 μ L PCR-buffer + 6.5 μ L TECHNO Taq-polymerase.

8.5 Vortex the tube with Taq-polymerase solution for 3-5 seconds and spin down drops for 3-5 sec. The maximum storage time for Taq-polymerase solution is 1 hour.

8.6 Add 10 μ L of Taq-polymerase solution into each tube (except background tubes). Avoid paraffin layer break.



When using the Rotor-Gene Q detecting thermal cycler for PCR, no mineral oil is added to the tubes!

8.7 Add one drop (~20 μ L) of mineral oil into each tube. Close tubes tightly.

8.8 Vortex the tubes with samples, "C-" and "C+" for 3-5 sec and spin down drops for 3-5 sec.

8.9 Add 5.0 μ L of cDNA sample into corresponding tube. Avoid paraffin layer break. Do not add DNA into the "C-", "C+" tubes. Avoid paraffin layer break.



Open the tube, add DNA sample, then close the tube before proceeding to the next DNA sample to prevent contamination. Use filter tips.

8.10 Add 5.0 μ L of "C-" which has passed NA isolation stage and reverse transcription reaction into "C-" tubes. Add 5.0 μ L of "C+" into corresponding tube. Avoid paraffin layer break.

8.11 Spin tubes/strips briefly (1-3 sec) at room temperature (not applicable to kits approved for use with Rotor-Gene Q thermal cycler).

8.12 Set the tubes/strips to the Thermal Cycler.

8.13 Launch the Thermal Cycler software and run PCR according to instructions supplied with device, considering 35 µl reaction mix volume. See tables 4-8 to refer the cycling program and table 9 to refer the detection channels (applicable to Real-Time PCR kits).

In case you use DTlite and DTprime thermal cyclers, launch the thermal cycler application in “Device operating” mode. Upload ini file before the first run. Add corresponding test in subsequent runs. Specify the number and identifiers of samples. Define position of tubes in software interface according to position they were set in thermal unit. Run RT-PCR.

Table 4. The PCR program for DTlite and DTprime Thermal Cyclers

Step	Temperature, °C	Min.	Sec.	Number of cycles	Optical measurement	Type of the step
1	94	5	00	1		Cycle
2	94	0	10	50		Cycle
	58	0	25		v	
	64	0	15			
3	10 ¹	Holding		Holding
¹ – holding at 25°C is allowed						

Table 5. The PCR program for iCycler iQ5 thermal cyclers (with persistent well factor)

Cycle	Repeats	Step	Dwell time	Setpoint, °C	PCR/Melt Data Acquisition
1	1				
		1	05:00	94,0	
2	50				
		1	00:10	94,0	
		2	00:25	58,0	Real Time
		3	00:15	64,0	
3	1				
		1	01:00	10,0	

Table 6. The PCR program for iCycler iQ thermal cyclers (Bio-Rad Laboratories)

Cycle	Repeats	Step	Dwell time	Setpoint, °C	PCR/Melt Data Acquisition
dynamicwf.tmo program					
1	1				
		1	00:30	80,0	
		2	05:00	94,0	
2	10				
		1	00:20	94,0	
		2	00:20	58,0	
		3	00:10	64,0	
3	2				
		1	00:20	85,0	Real Time
PCR program					
4	40				
		1	00:10	94,0	
		2	00:10	58,0	
		3	00:30	58,0	Real Time
		4	00:20	64,0	
5		10,0	Storage

Table 7. The PCR program for Rotor-Gene Q Thermal Cyclers

Cycling	Temperature	Hold Time	Cycle Repeats
Cycling	80 °C	300 sec	1 time
Cycling 2	94 °C	10 sec	50 times
	54 °C	5 sec	
	58 °C ²	25 sec	
	64 °C	20 sec	

Table 8. Detection channels

	Specific product	IC
DTprime, DTlite and IQ5	Fam	Hex
Rotor-Gene Q	Green	Yellow

² - take the measurement

9. CONTROLS

Table 9.

Control	The controlled step	Result	Interpretation
C+	PCR	Specific signal on Fam/Green is present and the value fits in the range	Valid
		Specific signal on Fam/Green is absent	Invalid*
C-	PCR and RNA extraction	Specific signal on Fam/Green is present	Invalid**
		Specific signal on Fam/Green is absent	Valid
IC	PCR and RNA extraction	Specific signal on Hex/Yellow is present and the Cp value fits in the range	Valid
		Specific signal on Hex/Yellow is absent	Invalid***

The sample is considered positive if the signal for specific cDNA is present. The signal for IC could be absent in samples with high concentration of specific cDNA due to competitive priming.

The sample is considered negative if the signal for specific cDNA is absent and for IC is present.

* - if the signal for C+ is absent or the value does not fit in the range, all tests of current batch must be repeated.

** - If the signal for C- is present or the Cp value does not fit in the range, the result cannot be reported to the patient and the test should be repeated for the sample.

10. DATA ANALYSIS

In case of using DNA-Technology made Real-Time PCR Thermal Cyclers the analysis is performed automatically. In all other cases the analysis is based on the presence or absence of specific signal. The controls should be also considered to exclude false positive and false negative results (see p. 7 of the current manual). The cutoff Ct values for Rotor-Gene Q thermal cyclers are 40 (specific product), 33 (C+) and 36 (IC). The result characterized by Ct above this value should be considered doubtful and the whole assay should be repeated.

The interpretation should be performed in accordance with table 10.

Table 10.

Test samples		Interpretation
HIV REAL-TIME PCR detection Kit		
Fam (Green for Rotor-Gene Q)	Hex (Yellow for Rotor-Gene Q) ³	
Test samples		
Cp/Ct is specified, for Rotor-Gene Q Ct<40	Not considered	Positive
Cp/Ct is not specified (for iQ N/A)	Cp/Ct 29-34, for Rotor-Gene Q Ct<36	Negative
Cp/Ct is not specified (for iQ N/A)	Cp/Ct is not specified (for iQ5 N/A), for Rotor-Gene Cp/Ct is not specified or Ct>36	Uncertain
Positive control		
Cp/Ct<33	Not considered	Positive
Negative control		
Cp/Ct is not specified (for iQ N/A)	Cp/Ct 29-34, for Rotor-Gene Q Ct<36	Negative

³ - if the Cp (Ct) value for HEX channel exceeds the indicated range the result should be considered uncertain.

11. TROUBLESHOOTING

Table 11.

	Specific signal +	Specific signal -	Possible cause	Solution
C+	-	-	Operation error PCR inhibition Violation of storage and handling requirements	Repeat PCR Dispose of the current batch
C-	+	+	Contamination	Dispose of the current batch Perform decontamination procedures
RNA-IC		-	PCR inhibition	Repeat PCR

If you face to any undescribed issues contact our customer service department:

Phone: +7(495) 640.16.93

E-mail: hotline@dna-technology.ru

<https://dna-technology.com/support>

12. STORAGE AND HANDLING REQUIREMENTS

Shelf life - 12 months if all the conditions of transportation, storage and operation are met.

All components of the **HIV REAL-TIME PCR detection Kit**, except paraffin sealed PCR-mix and positive control (C+), must be stored at minus 20 °C over the storage period.

The PCR-buffer and mineral oil can be stored at temperature between 2 °C and 8 °C.

The paraffin sealed PCR-mix and positive control (C+) must be stored at temperature between 2°C and 8 °C over the storage period.

The kit stored under undue regime must not be used.

The **HIV REAL-TIME PCR detection Kit** must be transported in thermoboxes with ice packs by all types of roofed transport at temperatures inside the thermoboxes corresponding to storage conditions of the kit components.

It is allowed to transport the kit, except for paraffin sealed PCR-mix and positive control (C+), in thermoboxes with ice packs by all types of roofed transport at the temperature inside the thermoboxes up to 25 °C for no longer than 5 days.

It is allowed to transport the paraffin sealed PCR-mix and positive control (C+) in thermoboxes with ice packs by all types of roofed transport at the temperature inside the thermoboxes from 2 °C to 25 °C for no longer than 5 days.

Reagent kits transported with violation of temperature conditions must not be used.

An expired **HIV REAL-TIME PCR Detection Kit** must not be used.

We strongly recommend following the instructions to get robust and reliable results.

The conformity of the **HIV REAL-TIME PCR Detection Kit** to the prescribed technical requirements is subject to compliance of storage, carriage and handling conditions recommended by manufacturer.

13. SPECIFICATIONS

- a. **Analytical specificity:** the **HIV REAL-TIME PCR Detection Kit** allows detection of HIV-1. The samples containing HIV-1 will be defined as positive. The samples not containing HIV-1 will be defined as negative.
- b. **Sensitivity:** not less than 200 copies of HIV DNA per 1 mL of blood plasma.
- c. **Diagnostic sensitivity:** 99,5%.
- d. **Diagnostic specificity:** 100%.



The claimed specifications are guaranteed when DNA extraction is performed with *PREP-NA* DNA/RNA Extraction Kit.

14. QUALITY CONTROL

The quality control procedures performed in accordance with ISO 9001:2015 and ISO 13485:2016:

- observation of quality management in manufacturing of products;
- creation of values for customers;
- maintenance of the best service quality and customer management.

Contact our customer service with quality issues of **HIV REAL-TIME PCR Detection Kit**.

Technical support:

E-mail: hotline@dna-technology.ru

<https://www.dna-technology.com>

Manufacturer:

"DNA-Technology Research & Production", LLC,

142281, Russia, Moscow Region,

Protvino, Zheleznodorozhnaya Street, 20

Phone/fax: +7(495) 640.17.71

E-mail: info@dna-technology.com

<https://www.dna-technology.com>

Seller: "DNA-Technology" LLC,

117587, Russia, Moscow,

int. ter. Municipal District Chertanovo Severnoye,














Varshavskoye shosse, 125 Zh, building 5, floor 1, office 12;

Phone/fax: +7(495) 640.17.71

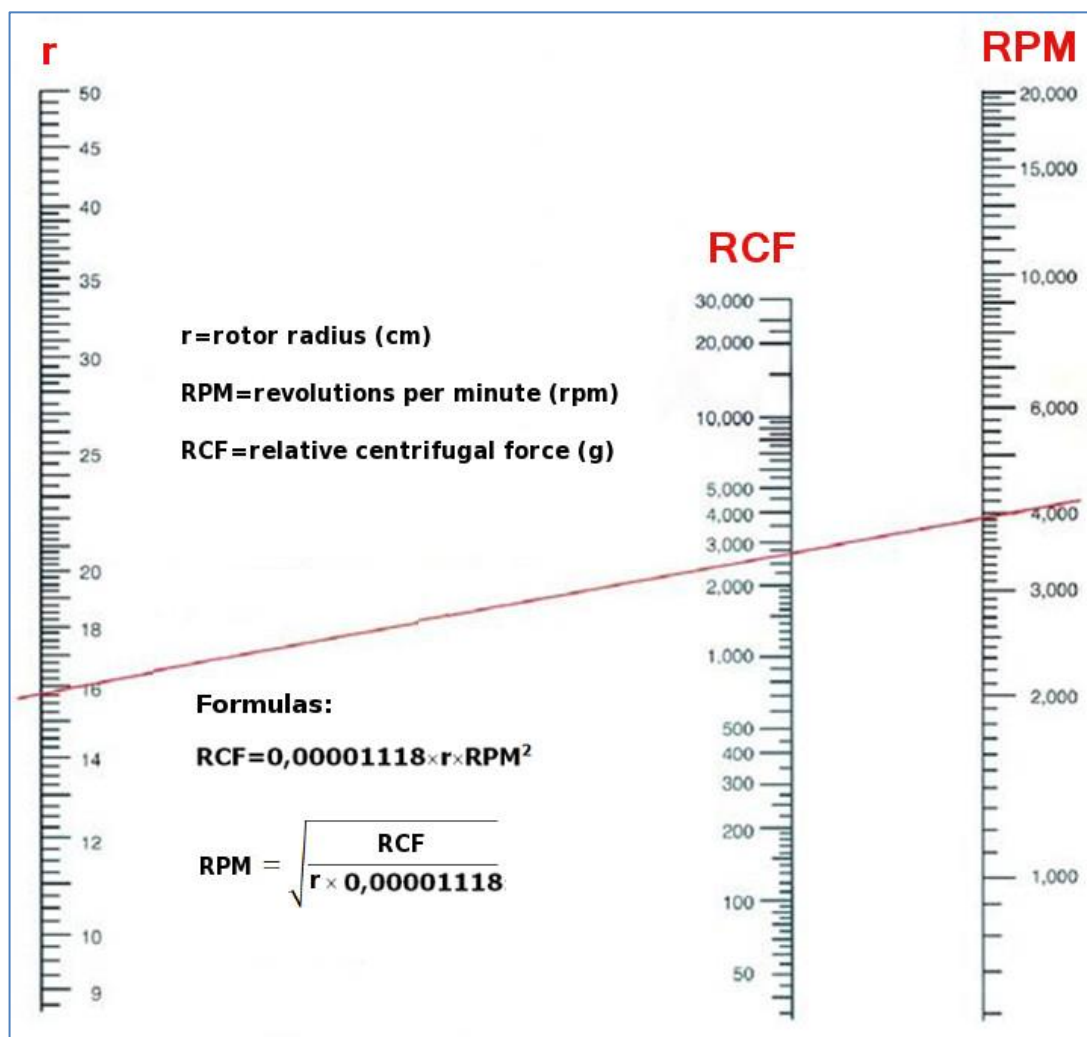
E-mail: info@dna-technology.com

<https://www.dna-technology.com>

15. KEY TO SYMBOLS

	For research use only		Date of manufacture
	Temperature limit		Consult instructions for use
	Contains sufficient for<n>tests		Catalogue number
	Use-by date		Manufacturer
	Batch code		Keep away from sunlight
	Version		Non-sterile
	Caution		

Nomogram and formula for calculation of relative centrifugal force (RCF) in the speed of rotation (RPM) depending of the rotor diameter



REF

R3-P609-23/9EU
R3-P609-S3/9EU

VER

311-4.2025.05.13